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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/423,126	11/05/99	BUCHTER-LARSEN	A	674509-2020

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HM12/0330

EXAMINER	
SOUAYA,J	
ART UNIT	PAPER NUMBER
1655	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/423,126	Applicant(s) Buchter-Larsen et al
	Examiner Jehanne Souaya	Group Art Unit 1655

☒ Responsive to communication(s) filed on *Nov 5, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-25* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. This is not an election of species. In the instant case, for claims 1-25, applicant must elect a single nucleic acid and corresponding amino acid sequence to be examined as these amino acid sequences appear to be drawn to different proteins.

Claims 1-25 are linking:

Group I: SEQ ID NO 1 and 7

Group II: SEQ ID NO 2 and 8

Group III: SEQ ID NO 3 and 9

Group IV: SEQ ID NO 4 and 10

Group V: SEQ ID NOS 5 and 11

Group VI: SEQ ID NOS 6 and 12

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Tom Kowalski on February 20, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-25, SEQ ID NOS 1 and 7. Affirmation of this election must be made by applicant in replying to this Office action. SEQ ID NOS 2-6 and 8-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a process for producing any anti-oxidant in any medium which comprises a component which is any plant (which could be a cereal or a fruit, such as a grape) or part thereof, wherein any recombinant enzyme (which may be a glucan lyase such as the amino acid of SEQ ID NO 1, or any variant, homologue or fragment thereof) is expressed in the plant or part thereof and acts on any glucan substrate which is present either in the medium and the component or in the component only to produce any anti-oxidant (which may be 1,5-D-anhydrofructose). The specification teaches that the invention provides a method of preparing *in situ* in an oxidizable medium an anti-oxidant. The specification teaches the amino acid sequence of 6 glucan lyases (SEQ ID NOS 1-6) which could be suitable for producing 1,5-D-anhydrofructose from starch (p.11).

With regard to the broadest interpretation of the claim, the specification, however, fails to teach the method of the claimed invention with regard to any recombinant enzyme expressed in any plant to produce any anti-oxidant from a glycan. Regarding the narrower interpretation of the claims to a specific glucan lyase such as SEQ ID NO1 or any variant, homologue, or fragment thereof, the specification only teaches 6 different glucan lyases. The specification does not teach variants or homologs or fragments of such glucan lyases, nor does the specification teach converting a glucan to anhydrofructose using any variant, homolog or fragment of proteins having SEQ ID NOS 1-6 as taught in the specification. Furthermore, the specification only presents the amino acid sequences in SEQ ID NOS 1-6 of the 6 possible glucan lyases, but does not teach their relationship to each other, ie are they homologs or variants of one another? The specification

only references WO publications where these glucan lyases can be found but does not appear to incorporate them by reference into the specification. Therefore the specification fails to teach how these glucan lyases are related to each other, let alone their ability to be expressed in plants to produce anhydrofructose from a glucan.

Additionally, although the specification teaches how to transform a plant such as maize or grape or potatoes with a glucan lyase, the specification does not teach having done so, nor does the specification teach having produced an anti-oxidant such as anhydrofructose from a glucan where the glucan is present in either the medium and the plant, or the plant only, using the methods taught in the specification. As set forth by the Court in *Vas Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date, applicant was in possession of the claimed invention. The specification teaches possession of the proteins of SEQ ID NOS 1-6, however the specification has not shown with reasonable clarity any variant, homolog or fragment of such sequences. Furthermore, the specification has not shown with reasonable clarity the production of any anti-oxidant in any medium which comprises a component which is any plant or part thereof, wherein any recombinant enzyme is expressed in the plant or part thereof and acts on any glucan substrate which is present either in the medium and the component or in the component only to produce any anti-oxidant. Although the specification teaches how to transform a plant such as maize or grape or potatoes with a glucan lyase, the specification does not teach having done so, nor does the specification teach having produced anhydrofructose from a glucan that is present in the

medium and the plant or in the plant itself wherein the glucan lyase is expressed in the plant. Each of the claimed invention is a broad genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112 first paragraph. Absent such a written description, the specification fails to show that applicant was "in possession of the claimed invention" at the time the application for patent was filed.

Indefinite

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-25 provide for the use of a glucan lyase or anhydrofructose, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is indefinite in the recitation of "which method comprises" as it is unclear if the "method" being referred to is the process for producing an antioxidant, or to a secondary method which is part of the overall process.

Claim 1 is indefinite in the recitation of "a process for producing an anti-oxidant in a medium comprising..." as it is unclear if the term "comprising" follows the process, ie: -- a

process comprising-- or if the term is meant to further limit the medium, ie: "the medium comprising a component which is a plant or part thereof".

Claims 1 and 17-18 are indefinite in the recitation of "a component which is a plant or part thereof" as it is unclear if the "part thereof" refers to the component or the plant. That is, can the component be composed of more than the plant, such that "or the part thereof' refers to part of the component and not necessarily part of the plant? If the component is only made up of the plant, and "part thereof' refers to part of a plant, it would be more clear to recite instead --a medium comprising a [component which is a] plant or part thereof--. Likewise, it is unclear if "expressing in the component or part thereof a recombinant enzyme" refers to expressing the recombinant enzyme in the plant, or in a part of the component which does not include the plant.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (US Patent 6,013,504, 102(e) date: 7/2/1996, hereinafter referred to as Yu(a)) or in the alternative, Yu et al (WO 95/10618, international publication date: April 20, 1995, hereinafter referred to as Yu(b)) in view of Poulsen (WO 97/04113) and Ishida et al (Nature Biotechnology, vol. 14, 1996, pp 745-750) and Perl et al (Nature Biotechnology, vol.14, 1996, pp 624-628).

The claims are broadly drawn to a process for producing any anti-oxidant in any medium which comprises a component which is any plant or part thereof, wherein any recombinant enzyme is expressed in the plant or part thereof and acts on any glucan substrate which is present either in the medium and the component or in the component only to produce any anti-oxidant. The claims are more narrowly drawn to producing 1,5-D-anhydrofructose in a medium wherein a glucan lyase such as the amino acid of SEQ ID NO 1, or any variant, homologue or fragment thereof is expressed in component of the medium which could be a cereal or a fruit, such as a grape. Both Yu(a) and Yu (b) teach the nucleic acid and amino acid sequences of glucan lyases that can convert α 1,4 glucan lyase to 1,5-D-anhydrofructose (Yu (a) see abstract, col 4, SEQ ID NOS 3 and 4, [SEQ ID NO 3 is identical to SEQ ID NO 1 of the instantly claimed invention];

Yu(b) abstract, p.p. 17, 19, SEQ ID NOS 1-4, [SEQ ID NO 3 is identical to the instantly claimed SEQ ID NO 1]). Yu (a) and Yu (b) teach expression of this glucan lyase in microorganisms (Yu (a) see col. 14, Yu (b) see p 23) and teach that lyase activity (production of anhydrofructose) was observed in the medium with both *Pichia pastoris* and *Aspergillus niger* (see col. 14 of Yu(a) and p. 27 of Yu(b)). Yu (a) and u(b) further teach that these results indicate that active lyase was secreted from the cells and that the lyase activity was also measured in cell free extract (Yu (a) col. 15, Yu (b) p. 27-27). Yu (a) and Yu(b) also teach that instead of Aspergillus niger as host, preferred embodiments include any transformed host organism having the capability of producing AF as a consequence of the introduction of a DNA sequence, and further teach contemplating a method for preparing 1,5-D-anhydrofructose by contacting α 1,4 glucan with α 1,4 glucan lyase expressed in a transformed host organism by transforming the host organism with a nucleic acid described in Yu (a) and Yu (b) (Yu (a) see col. 16, lines 25-30 and 37-40; Yu (b) see p. 29).

Although neither Yu (a) nor Yu(b) teach transforming a plant with SEQ ID NO 1, Yu (a) and Yu(b) provide motivation for the ordinary artisan to do so in contemplating the transformation of any host organism that can produce anhydrofructose. The ordinary artisan would have further been motivated to produce anhydrofructose as Yu (a) teaches that anhydrofructose can be a precursor for the preparation of the antibiotic pyrone microthecin (see col. 1, lines 17-20). As applicants have stated in the instant specification, methods of transforming plants was widely known in the art and was readily practiced at the time of the invention. Poulsen teaches transformation of potatoes (pages 24-28), Ishida teaches

transformation of maize, and Perl et al teaches the transformation of grapes. Therefore it would have prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the method of Yu (a) or Yu(b) to transform potatoes or maize or grapes to express α 1,4 glucan lyase to produce anhydrofructose, as Yu a &b teach the successful transformation of microorganisms to express α 1,4 glucan lyase and produce anhydrofructose and teach that such a method could be used to transform any host organism capable of producing anhydrofructose. The ordinary artisan would have considered the transformation of plants to be equivalent host organisms and would have been enabled in a method of transforming a plant to express a glucan lyase as 1)Yu a&b both teach how to transform an organism, ie teach the nucleic acid sequences of glucan lyases that can produce anhydrofructose, and 2) the state of the art was very high at the time the invention was made as to how to successfully transform plants to express an enzyme of interest.

Conclusion

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaye

Jehanne Souaya
Patent examiner
March 20, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
3/26/01